

*Amendment and Response to Office Action*  
*U.S. Serial No.: 10/619,091*  
*Filed: July 14, 2003*  
*Page 7 of 14*

### **REMARKS**

Claims 1-8 and 16-23 are pending. Claims 9-15 have been cancelled as being drawn to a non-elected invention. Claims 1-8 and 16-20 have been amended and new Claims 21-23 added. Support for the amendments and new claims can be found in the specification and original claims as filed. Therefore, no new matter has been added. Favorable consideration of the currently pending claims is respectfully requested in light of the foregoing amendments and following remarks.

#### ***Elections/Restrictions:***

Applicant confirms the April 19, 2006 telephone election of Group III, Claims 1, 6-8 and 16-20, drawn to a method for sorting test strips via a magnetic field, classified in class 209, subclass 214. Claims 2-5 have been amended to depend from Claim 16. Claims 9-15 have been cancelled without prejudice as being drawn to a non-elected invention and may be pursued in a divisional application.

#### ***Claim Objections:***

In the Office Action, Claims 16 and 18 were objected to for informalities. These claims have been amended and, accordingly, applicant requests that the objection of Claims 16 and 18 be withdrawn.

#### ***Rejections Under 35 U.S.C. § 112***

In the Office Action, Claims 19 and 20 were rejected as being indefinite under 35 U.S.C. § 112, second paragraph. Applicant has amended Claim 19 to depend from Claim 18 and has amended Claim 20 to clarify that the test strips are counted as they enter the container, as suggested by the Examiner. Accordingly, applicant submits that the amended claims are definite and requests that the rejection of Claims 19 and 20 under 35 U.S.C. § 112 be withdrawn.

*Amendment and Response to Office Action*  
*U.S. Serial No.: 10/619,091*  
*Filed: July 14, 2003*  
*Page 8 of 14*

### ***Rejections Under 35 U.S.C. § 102***

In the Office Action, the Examiner rejected Claims 1, 6 and 16 under 35 U.S.C. § 102(b) as being anticipated by Rohr (U.S. Patent No. 5,445,971). Applicant respectfully submits that the amendments to the claims overcome the rejection.

Claim 1 has been amended to clarify that the magnetically attractive material is present at one or more **locations** on the strip such that the strip moves or adopts a specific spatial orientation or alignment when exposed to a magnetic field. Claim 16 depends from amended Claim 1.

Applicant submits that Rohr fails to disclose all of the limitations of amended Claims 1 and 16. Specifically, Rohr fails to disclose a test strip containing a magnetically attractive material at one or more **locations** on the test strip. As noted by the Examiner, Rohr discloses only that the reaction of magnetic material in response to a magnetic field is dependent on the **amount** of magnetic material present.

Claim 6 has been amended to recite a plurality of test strips in which a first test strip has a magnetically attractive material and exhibits a response to a magnetic field and a second test strip has substantially **no** magnetically attractive material and exhibits substantially **no** response to a magnetic field.

Applicant submits that Rohr fails to disclose all of the limitations of Claim 6 as amended above. Specifically, Rohr fails to disclose a second test strip having substantially **no** magnetically attractive material and substantially **no** response to a magnetic field. As noted by the Examiner and explained above, Rohr discloses only that the reaction of magnetic material in response to a magnetic field is dependent on the **amount** of magnetic material present.

Accordingly, applicant submits that Rohr fails to anticipate Claims 1, 6 and 16 and respectfully requests that the rejection under 35 U.S.C. § 102(b) be withdrawn.

*Amendment and Response to Office Action*  
*U.S. Serial No.: 10/619,091*  
*Filed: July 14, 2003*  
*Page 9 of 14*

The Examiner rejected Claims 1, 16 and 17 under 35 U.S.C. § 102(e) as anticipated by Hagen *et al.* (U.S. Patent No. 6,872,358) (hereinafter "Hagen"). Applicant respectfully submits that the amendments to the claims overcome the rejection.

As mentioned above, Claim 1 has been amended to clarify that the magnetically attractive material is present at one or more **locations** on the test strip.

Hagen discloses a test strip dispenser in which the test strips include "magnet means" and the dispenser includes an engaging element for magnetically engaging and moving the test strips. However, Hagen fails to disclose or suggest test strips having magnetically attractive material at one or more **locations** on the strip to facilitate their alignment or orientation when exposed to a magnetic field as claimed in amended Claim 1. Claims 16 and 17 depend, directly or indirectly, from amended Claim 1 and contain all the limitations thereof.

For at least the foregoing, applicant respectfully submits that Claims 1, 16 and 17 are patentable over Hagen and requests that the rejection of Claims 1, 16 and 17 under 35 U.S.C. § 102(e) be withdrawn.

### ***Rejections Under 35 U.S.C. § 103***

In the Office Action, the Examiner rejected Claims 1 and 6-8 under 35 U.S.C. § 103(a) as being obvious over van Rijckevorsel *et al.* (U.S. Patent No. 4,578,716) (hereinafter "van Rijckevorsel") in view of Landsdorp *et al.* (U.S. Patent No. 5,514,340) (hereinafter "Landsdorp"). Applicant respectfully submits that the amendments to the claims overcome the rejection.

Claim 1 has been amended as described above to clarify that the magnetically attractive material is present at one or more **locations** on the test strip. Claim 6 has been as described above to recite a plurality of test strips in which a first test strip has a magnetically attractive material and exhibits a response to a magnetic field and a second test strip has substantially **no** magnetically attractive material and exhibits substantially **no** response to a

*Amendment and Response to Office Action  
U.S. Serial No.: 10/619,091  
Filed: July 14, 2003  
Page 10 of 14*

magnetic field. Claims 7-8 depend from amended Claim 6 and contain all the limitations thereof.

Van Rijckevorsel discloses a method for **manually** sorting faulty test strips from non-faulty test strips. As acknowledged by the Examiner, van Rijckevorsel fails to disclose the use of a magnetic field to sort test strips. In addition, van Rijckevorsel fails to disclose test strips in which magnetically attractive material is present at one or more **locations** on the strip to facilitate strip orientation or alignment as claimed in amended Claim 1. Furthermore, van Rijckevorsel fails to disclose a plurality of test strips in which a first test strip has a magnetically attractive material and a second test strip has substantially no magnetically attractive material as claimed in amended Claim 6.

Landsdorp discloses a method for separating magnetically labeled **cells** from a **sample** using a magnetic field. The Examiner asserts that in view of van Rijckevorsel and Landsdorp it would have been obvious to mark faulty test strips with magnetic labels and use a magnetic field to separate faulty test strips from "superior" test strips.

Applicant respectfully disagrees and submits that the combination of van Rijckevorsel and Landsdorp is improper for the foregoing reasons and at least the following reasons: 1) Landsdorp is not analogous art to the subject matter of the present application; and 2) neither van Rijckevorsel nor Landsdorp provide any teaching, suggestion or motivation for combining the methods of separation disclosed in van Rijckevorsel with the test strips, and methods for making the test strips, disclosed in Landsdorp.

Applicant asserts that the field of Landsdorp, directed to methods for depleting selected cells such as T lymphocytes, tumor cells or red blood cells from a sample such as blood or bone marrow (col. 4, lines 59-61), is not **reasonably pertinent** to the field of the present application, which is directed to test strips and methods of sorting test strips. *See* MPEP § 2141.01(a); *In re Clay*, 966 F.2d 656, 659, 23 U.S.P.Q. 2d 1058, 1060-61 (Fed. Cir. 1992) ("A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals,

*Amendment and Response to Office Action*  
*U.S. Serial No.: 10/619,091*  
*Filed: July 14, 2003*  
*Page 11 of 14*

logically would have commended itself to an inventor's attention in considering his problem."'). Landsdorp discloses a complex apparatus for removing magnetically labeled cells from a sample, the apparatus having multiple elements, filter chambers and flow distribution means (col. 4, lines 27-58). Landsdorp also discloses a method of using this apparatus to deplete selected cells from a sample such as blood or bone marrow (col. 4, line 59 to col. 5, line 5). Applicant submits that a person having ordinary skill in the art would not reasonably have expected to solve the problem of sorting faulty test strips from non-faulty test strips by considering a reference dealing with depleting selected cells from blood or bone marrow. *See also In re Clay*. A reference is not in an analogous field to that of the present application simply because it uses a magnet to separate one thing from another.

Moreover, applicant asserts that there is no teaching, suggestion or motivation to combine van Rijckevorsel with Landsdorp, "either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art." MPEP § 2143.01. As discussed above, van Rijckevorsel discloses a method for manually sorting faulty test strips from non-faulty test strips. Van Rijckevorsel provides no suggestion that the methods disclosed therein for sorting test strips is lacking or in need of improvement, and, accordingly, a person of ordinary skill in the art would not have been motivated to look elsewhere for this teaching. And, certainly, a skilled artisan would not be motivated to look to a reference directed to a method for magnetically separating magnetically labeled cells from a sample such as blood or bone marrow.

Accordingly, applicant submits that van Rijckevorsel and Landsdorp cannot be properly combined to render Claims 1 and 6-8 obvious under 35 U.S.C. § 103(a). Applicant therefore respectfully requests that the rejection of these claims be withdrawn.

Claim 18 was rejected under 35 U.S.C. § 103(a) as obvious over Hagen in view of Caladine (GB 2,170,780). Applicant respectfully submits that the amendments to the claims overcome the rejection.

*Amendment and Response to Office Action*  
*U.S. Serial No.: 10/619,091*  
*Filed: July 14, 2003*  
*Page 12 of 14*

As mentioned above, Claim 1 has been amended to clarify that the test strip has a magnetically attractive material at one or more **locations** on the strip. Claim 18 depends from amended Claim 1 and is a method of counting the test strips of Claim 1 by applying a magnetic field to the test strips to cause them to move and counting the strips as they move in response to the magnetic field.

Hagen discloses a test strip dispenser in which the test strips include "magnet means" and the dispenser includes an engaging element for magnetically engaging and moving the test strips. Hagen fails to disclose or suggest test strips having magnetically attractive material at one or more **locations** on the strip as claimed in amended Claim 1 from which Claim 18 depends.

Caladine describes a dispensing device having a counting mechanism, such as an alcoholic beverage dispenser for counting the number of drinks dispensed. In contrast to the claimed counting method in which the application of a magnetic field to the test strips causes the strips to move and be counted, the magnet (40) taught by Caladine closes a reed switch (43) to complete a count input circuit. Therefore, the magnet taught by Caladine fails to measure the **movement** of a magnetically attractive material as claimed in the present application.

For at least the foregoing, applicant submits that Claim 18 is non-obvious over Hagen in view of Caladine and respectfully requests that the rejection of this claim under 35 U.S.C. § 103(a) be withdrawn.

Claims 19 and 20 were rejected under 35 U.S.C. § 103(a) as obvious over Hagen and Caladine and further in view of Nambu (U.S. Patent No. 5,444,749). Applicant respectfully submits that the amendments to the claims overcome the rejection.

Claims 19 and 20 depend from Claim 18, which depends, directly or indirectly, from amended Claim 1 and include all of the limitations thereof. Moreover, Nambu fails to cure the deficiencies of the other prior art of record discussed above.

*Amendment and Response to Office Action*  
*U.S. Serial No.: 10/619,091*  
*Filed: July 14, 2003*  
*Page 13 of 14*

Accordingly, because Claim 18 and amended Claim 1 are believed to be allowable over the prior art of record, Claims 19 and 20 are also believed to be allowable, and applicant respectfully requests that the rejection of these claims under 35 U.S.C. § 103(a) be withdrawn.

***New Claims***

New Claims 21-23 have been added. These claims depend from amended Claim 6. Support for these claims can be found at least in Claims 18-21 as originally filed and do not contain new matter.

*Amendment and Response to Office Action  
U.S. Serial No.: 10/619,091  
Filed: July 14, 2003  
Page 14 of 14*

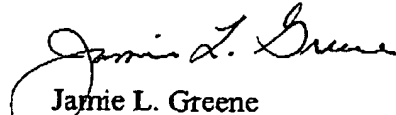
### CONCLUSION

Based upon the amendments and remarks provided above, applicant believes that Claims 1-8 and 16-23 are in condition for allowance. A Notice of Allowance is therefore respectfully solicited.

No additional fees are believed due; however, the Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment, to Deposit Account No. 11-0855.

If the Examiner believes any informalities remain in the application that may be corrected by Examiner's Amendment, or there are any other issues that can be resolved by telephone interview, a telephone call to the undersigned attorney at (404) 815-6500 is respectfully solicited.

Respectfully submitted,

  
Jamie L. Greene  
Reg. No. 32,467

KILPATRICK STOCKTON LLP  
1100 Peachtree Road, N.E.  
Suite 2800  
Atlanta, Georgia 30309-4530  
Telephone: (404) 815-6500  
Attorney Docket No. 45738/286749 (SDI-0541)